REMARKS

Claims 1-29 were pending in the application. Claims 1-6 and 12-28 have been cancelled, and new independent claim 30 and dependent claim 31 have been added. Claim 29 has been amended to focus on a kit comprising reagents for nucleic acid based methods for determining haptoglobin genotype, and dependent claims 7 amended to depend from it. New claim 30 is focused on a kit comprising reagents utilizing antibody based methods for determining haptoglobin phenotype.

In addition, new claims 33-34 and 35-36 are added focused on kits for generally determining genotype and phenotype of haptoglobin, respectively, using nucleic acid and antibody based methods, respectively.

Applicant has also amended the specification to provide an updated cross-reference section, in which the instant application is indicated as a continuation-in-part of co-pending application serial no. 10/748,177, filed December 31, 2003.

Information Disclosure Statement

Applicant believes that with the linking of the instant application with the co-pending application mentioned above, the requirement for an information disclosure statement filed in the parent application is incorporated.

Claim Rejections - 35 USC § 112-Scope of Enablement

Claims 2-14, 29 have been rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a kit comprising reagents for determining haptoglobin phenotype of a diabetic patient and a kit with the intended use of determining a potential of a diabetic patient to benefit from vitamin E therapy for treatment of CV death or MI wherein the benefit from said vitamin E therapy to a patient having a haptoglobin 2-2 phenotype is greater compared to patients having haptoglobin 1-2 phenotype or 1-1 phenotype, does not reasonably provide enablement for a kit for determining a potential of a diabetic patient to benefit from any anti oxidant therapy for treatment of any vascular complication wherein the benefit. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant has amended claim 29 to encompass the scope of antioxidant to vitamin E, and the scope of vascular complication to cardiovascular death and myocardial infarction. Furthermore, Applicant has amended the "treatment" to "prevention", as supported, *inter alia*, by the title of the application and the specification on page 1, line 7, and page 10, lines 5-7.

Claim Rejections· 35 USC § 102

Claims 2-14, 29 have been rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Levy (US 6,613,519, September 2, 2003). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. With regard to the limitation that the kits contain instructions, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004) (holding that an inventor could not patent known kits by simply attaching new set of instructions to that product). Here, reagents for determining a haptoglobin phenotype meets this. Levy teaches kit for evaluating a risk of a diabetic patient to develop cardiovascular disease (CVD). The kit comprises packaged reagents for determining a haptoglobin phenotype of the diabetic patient. Levy specifically outlines the haptoglobin phenotyping protocol in Col. 17. Levy teaches methods using nucleic acids including ASO probes, PCR, CPR, DGGE/TGGE (limitations of Claims 7-11). Moreover, Levy teaches immunological detection methods such as ELISA and FACS (col. 14). With respect to Claims 2-5, these limitations do not further limit the reagents in the kit, but limit the intended use. As noted above, intended use does not distinguish the prior art from the claimed invention. Thus, the Examiner asserts that Levy specifically teaches packaging reagents for determining a haptoglobin phenotype in a kit.

Applicant respectfully requests reconsideration of the rejection in light of the current application being linked to the 6,613,519 application as a continuation-in-part, rendering the

rejection moot. Applicant notes that the instant application and a descendent of the '519 application were co-pending at the time of filing of the instant application.

Claims 2-7, 12-14, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by DeLanghe (WO 9837419, August 27, 1998). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. With regard to the limitation that the kits contain instructions, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336,70 U.S.P.Q.2d 1862 (Fed. Cir. 2004) (holding that an inventor could not patent known kits by simply attaching new set of instructions to that product). Here, reagents for determining a haptoglobin phenotype meets this. DeLanghe teaches a method and kit for determining a haptoglobin phenotype and specifically relates to applications involving human haptoglobin. DeLanghe in fact teaches a kit for determining the phenotype of a haptoglobin comprising a binding partner (see Claim 20) (limitations of Claims 12-14). With respect to Claims 2-5, these limitations do not further limit the reagents in the kit, but limit the intended use. As noted above, intended use does not distinguish the prior art from the claimed invention. Thus, the Examiner asserts that Delanghe specifically teaches packaging reagents for determining a haptoglobin phenotype in a kit.

Applicant requests reconsideration of the rejection in light of the amendments to the claims and the comments below. First, Applicant has amended the pending claims to focus on kits that comprise nucleic acid based reagents and methods for determining haptoglobin genotype. As DeLanghe is silent on nucleic acid based methods, Applicant believes that claims 8-11 and 29 are not anticipated thereby. Applicant also believes that new claims 33 and 34, which do not include intended uses, are also not anticipated by DeLanghe.

With regard to immunological detection methods for haptoglobin gene product, Applicant provided the haptoglobin phenotype kit as new claim 30 and dependent claims 31 and 32. The scope of claim 30 is to a kit that includes an antibody for determining haptoglobin phenotype. Claim 31, including the subject matter of cancelled claim 14, include some methods utilizing

antibodies. New claim 32 indicates that the antibody is specific to at least one of Hp 1-1 or Hp 2-2, as supported by the specification on page 28, line 30 to page 29 line 1.

The teachings of Delanghe focus specifically on an agglutination-based assay method employing the T4 antigen of the bacterium *Streptococcus pyogenes* that comprises a haptoglobin binding site. The instant claims are focused on kits employing antibody reagents. Applicants believe that the amended claims are not anticipated by DeLanghe, and withdrawal of the rejection is requested. Applicants also believe that new claims 35 and 36, which do not include intended uses, are also not anticipated by DeLanghe.

If the Examiner has any questions or comments as to this response, the undersigned may be contacted at the address and telephone number below.

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Respectfully submitted,

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